American National Standard

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Manual, electronic, or automated sphygmomanometers

AAMI Association for the Advancement of Medical Instrumentation

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Manual, electronic, or automated sphygmomanometers

Developed by
Association for the Advancement of Medical Instrumentation

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Abstract: This standard establishes labeling, safety, and performance requirements for sphygmomanometers, including electronic, electromechanical, and nonautomated devices that are used in the indirect measurement of blood pressure. Ambulatory blood pressure monitors, which are portable, lightweight, automated devices worn or carried by the patient that are able to obtain and store the results of repeated determinations of blood pressure and heart rate during activities of ordinary daily living, also are included in the scope of this document.

Keywords: blood pressure, electromedical equipment, heart rate, sphygmomanometer

4.4.5 Overall system efficacy—Automated systems

See 4.4.5.B.

4.5 Requirements for inflation source and pressure control valves

4.5.1 Inflation source

The inflation source shall be capable of supplying sufficient air to bring a volume of at least 200 cm^3 (12 cubic inches) to a pressure of 300 mmHg in no more than 10 s, unless otherwise stated.

4.5.2 Manually adjustable valve

4.5.2.1 Pressure drop

With the valve closed, the maximum pressure drop with a volume of no more than 80 cm^3 shall be 1 mmHg in 10 s at initial differential pressures of 250 mmHg, 150 mmHg, and 50 mmHg.

4.5.2.2 Valve/cuff exhaust rate

The valve shall be adjustable and shall allow pressure reduction to be controlled and maintained at a rate between 2 mmHg/s and 3 mmHg/s, from initial differential pressures of 250 mmHg, 150 mmHg, and 50 mmHg.

4.5.2.3 Release rate

During the rapid exhaust of the pneumatic system with fully-opened valve, the time for the pressure reduction from 260 mmHg to 15 mmHg shall not exceed 10 s.

For blood pressure-measuring systems having the capability to measure in a neonatal mode, the time for the pressure reduction from 150 mmHg to 5 mmHg during the rapid exhaust of the pneumatic system with fully-opened valve shall not exceed 5 s.

4.5.3 Self-bleeding pressure control valve

4.5.3.1 Pressure drop

With the valve closed, the maximum pressure drop with a volume of no more than 80 cm^3 shall be 1 mmHg in 10 s at initial differential pressures of 250 mmHg, 150 mmHg, and 50 mmHg.

4.5.3.2 Valve/cuff exhaust rate

When the valve is in the self-bleeding position and when it is used with the cuff for which it is intended, it shall not be possible to reduce the cuff pressure at a rate lower than 2 mmHg/s throughout the 250 mmHg to 50 mmHg range.

4.5.3.3 Release rate

During the rapid exhaust of the pneumatic system with fully-opened valve, the time for the pressure reduction from 260 mmHg to 15 mmHg shall not exceed 10 s.

For blood pressure-measuring systems having the capability to measure in a neonatal mode, the time for the pressure reduction from 150 mmHg to 5 mmHg during the rapid exhaust of the pneumatic system with fully-opened valve shall not exceed 5 s.

4.5.4 Automated valves

see 4.5.4.B.

4.6 Requirements for the inflatable bladder and cuff

4.6.1 Inflatable bladder

4.6.1.1 Dimensions

The cuff bladder length should be approximately 0.80 times the circumference of the limb at the midpoint of the intended range of the cuff. The width of the cuff bladder should be optimally 0.40 times the circumference of the limb at the midpoint of the intended range of the cuff.

If manufacturers of automated devices supply cuffs that are outside of this range or are intended for use on a site other than the upper arm, they shall produce data verifying the accuracy of the system.

Blood pressure ranges for the study populations

For the auscultatory validation method, the systolic and diastolic blood pressure ranges specified for the subject database challenge the device to measure pressure accurately over a range of values normally encountered in both healthy and hypertensive individuals. The specified blood pressure ranges are not so wide, however, as to create extraordinary difficulties in enrolling subjects.

Recording of data/multiple measurements

For any study, it is possible to obtain multiple measurements for comparison of blood pressure data from the instrument under test and the reference standard. A single set of measurements per study should be used. For cuff/stethoscope auscultation, however, it has long been clinical practice to obtain several (usually 3) blood pressure readings from an individual in order to take into account the many factors contributing to variability in readings. For these same reasons, the procedure described in 5.2.5 requires that 3 separate sets of measurements be recorded for each individual. Each measurement set (minimum of 255 for stationary, 765 for ambulatory) is then used to calculate differences in the mean and standard deviation across the entire database.

For the intra-arterial method, it is valuable to use many more measurements per subject, since a total of 15 subjects can satisfy the minimum requirements. During catheterization, variations in blood pressure measurement are not uncommon; there is sufficient time to record at least 10 sets of observations of diastolic and systolic values, and this is what is recommended. Thus, a minimum of 150 observations of systolic and of diastolic paired values will be available for determining mean difference and standard deviation.

Mean values

Diagnoses and judgments on effectiveness of therapy usually have been based on systolic and diastolic blood pressures. Although these measures are unquestionably important in evaluating the health of an individual, the physiologic effectiveness of tissue perfusion can be determined better by mean blood pressure. With nonautomated auscultatory methods, a mean only can be estimated in an individual, often with poor accuracy. Automated measuring methods potentially can determine mean blood pressure at least as accurately as systolic or diastolic values.

The committee therefore recommends that manufacturers disclose, in a form similar to that provided for systolic and diastolic blood pressures, the capabilities of their instruments for determining mean pressures. Following mean pressures in individuals might be a distinguishing and valuable medical contribution of automated sphygmomanometry.

A.4.5 Requirements for inflation source and pressure control valves

Cuff and bladder size affects measurement accuracy when using the nonautomated technique, defined in this document as the reference standard method. (Cuff and bladder dimensions for nonautomated instruments are defined in normative reference 2.1.) The appropriate cuff and/or bladder sizes for electronic or automated sphygmomanometers can differ from those sizes designated in normative reference 2.1, as long as the manufacturer tests these cuffs according to the requirements of this standard. Users of automated monitors should be aware that they should use only cuffs that have been tested with the automated device they are using. Therefore, this standard does not specify cuff and bladder dimensions, but leaves these to the manufacturer.

For safety considerations, it is important to provide for a maximum time during which the cuff is inflated beyond 10 mmHg. There is no evidence to indicate that rate of deflation has a bearing on safety. Thus, the committee determined that deflation rate need not be considered for automated systems, although it is obviously important for the cuff/stethoscope method. If the automated instrument operates with a cuff deflation rate that is incompatible with that required for the cuff/stethoscope method, same-limb measurements are not possible for determining overall system efficacy.

A.4.5.1 Inflation source

Cuff inflation rates that are too low can cause venous congestion, in which case accurate detection of the Korotkoff sounds can be affected and there can be some effect on the diastolic pressure measurement. The minimum cuff inflation rate specified in 4.5.1 is representative of current practice. As a practical matter, it is not possible to inflate a cuff manually at a rate high enough to cause a startle response or serious discomfort to the patient; consequently, a maximum cuff inflation rate has not been specified.

A.4.5.2 Manually adjustable valve

The recommended rate of pressure release established by the American Heart Association is 2 mmHg/s to 3 mmHg/s (AHA, 1981). To ensure that the valve can control this rate, the maximum valve leakage should not exceed one-half (1 mmHg/s) of the minimum acceptable rate, as determined in a total system under operating

conditions. The volume of the smallest cuff in normal use (excluding the neonatal cuff) is approximately 80 cm^3. The leakage should be measured at 3 pressures throughout the range to verify proper functioning of the check valve within the adjustable valve, particularly at the lower pressures.

A standard adult cuff has an in-use volume of approximately 200 cm^3. After the diastolic pressure is determined, the compression should be released on the limb as rapidly as possible. Occasional emergencies also necessitate rapid reduction of the bladder pressure to facilitate immediate removal of the cuff. Since the diastolic pressure is usually less than 90 mmHg, a valve meeting the requirements of 4.5.2.3 should function satisfactorily at lower pressures.

A.4.6 Requirements for the inflatable bladder and cuff

The combined blood pressure cuff and bladder act as the interface between the patient and manometer and could introduce major errors, either through improper design of the cuff or bladder or through improper application of the system by the user. The design of the inflation system should take into consideration the user's ability to apply it routinely with the bladder centered over the artery to be compressed.

In order to minimize measurement errors attributable to the design of the inflation system, dimensional and performance requirements were developed for the inflatable bladder, cuff, and cuff with integral bladder.

A.4.6.1 Inflatable bladder

A.4.6.1.1 Dimensions

The AAMI Sphygmomanometer Committee strongly favors bladder dimension specifications that are compatible with the AHA's recommendations. Unfortunately, controversy over the optimum dimensions has persisted, resulting in a lack of consistency in AHA-published recommendations since 1967. This controversy exists largely because of the paucity of experimental data.

History

Until 1981, it had long been the recommendation of the AHA that:

> The inflatable bag should be long enough to go one-half way around the limb, if care is taken to put it directly over the compressible artery. A bag 30 cm in length, which nearly (or completely) encircles the limb, obviates any risk of misapplication. Several investigators have found that cuff bladders of 35 to 40 cm in length provide a closer approximation of intra-arterial diastolic blood pressure and a reduction in random error (AHA, 1967).

In 1981, however, the AHA published revised recommendations on indirect blood pressure measurement (AHA, 1981). Shortly after the publication of the revised AHA recommendations, Dr. Walter Kirkendall, a member of both the AHA and AAMI committees, was asked by the AAMI committee leadership to summarize the relationship between the AHA and AAMI recommendations with respect to bladder dimensions. On February 22, 1982, Dr. Kirkendall contributed the following statement to the AAMI committee record:

> AAMI proposed standards for nonautomated sphygmomanometers . . . tend to maintain the status quo. The recommendations from the American Heart Association recognize the evidence that bladders, which are relatively long and cover approximately 80 % of the circumference of the arm or more, give somewhat more reliable estimates of the intra-arterial pressures. Obviously, in the [AHA] recommendations, not all of the bladders would extend over 80 % of the circumference of the arm, but the trend in the recommendations is for the longer bladder to be used. The major difference in the two sets of recommendations is that the recommendations concerning length in the AAMI statement generally tend to recommend a shorter bladder. The AAMI statement concerning width of the bladder is consistent with the AHA recommendations.
>
> I will not repeat [the AHA] committee's reasons for recommending the bladder dimensions for blood pressure cuffs published in the AHA Committee Report. One of the major considerations would be to improve standardization of equipment so that the likelihood of obtaining reproducible results from one clinic to another would be greater. Nevertheless, the Committee is well aware that there [are] major unanswered questions concerning bladder dimensions, including:
>
> — Optimal length of the bladder to reflect intra-arterial pressure;
>
> — Optimal widths of the bladder; and
>
> — Whether thickening, hardening, or other similar changes of the brachial artery [occurring] in the elderly limits efficiency of the recommended bladders.

Although the cleaning and disinfection of cuffs is outside the scope of this document, Stemlicht (1990) and others have published information regarding the risk of cross contamination from blood pressure cuffs.

A.4.6.1.2 Pressure capacity

A range of 0 mmHg to a minimum of 260 mmHg has been adopted as a minimum requirement for the manometer used in the blood pressure measurement. It is quite probable, however, that the bladder will be included in a system expected to perform satisfactorily at pressures as high as 300 mmHg. A 10 %-over-range protection for the bladder and integral tubing seems reasonable.

A.4.6.2 Cuff

See also A.4.6.1.

A.4.6.2.1 Dimensions

The cuff width should accommodate the width of the bladder. The AHA has recommended widths and lengths for seven bladder sizes (AHA, 1981) and has stated that for contact closure cuffs and hook cuffs, "the full width should extend beyond the end of the inflatable bladder for about 25 cm" (AHA, 1967). This statement refers to an adult cuff incorporating a bladder 24 cm in length (as per AHA recommendations). Since the AHA publication further recommends that the bladder be of sufficient length "to go one-half way around the limb," it follows that the cuff should maintain its full width while completely encircling the limb. It is believed that maintenance of the full cuff width throughout the cuff's contact with the limb will minimize discomfort to the patient. The AHA further recommends that if the cloth bandage cuff is used, it should be long enough to encircle the arm several times with its full width extending beyond the end of the inflatable bladder for about 12 cm and then gradually tapering for an additional 40 cm (AHA, 1981).

A.4.6.2.2 Pressure capacity

The AHA (1981) recommendations further indicate, "The cuff should be made of nondistensible material, so that as far as possible, an even pressure is exerted on the extremity under the cuff." Furthermore, ECRI reported (1975) that "the cuff should not stretch nor allow the bag to balloon. Ballooning reduces the effect of bag width and may cause erroneously high pressure readings." Therefore, the bladder, when inflated to its maximum usable pressure, should be completely retained in the cuff.

A.4.6.2.3 Cuff closures/construction

See A.4.2.4 and A.4.6.2.2.

A.4.6.3 Cuff with integral bladder

See A.4.6.1 and A.4.6.2.

A.4.6.3.1 Dimensions

See A.4.6.2.1.

A.4.6.3.2 Pressure capacity

See A.4.6.2.2.

A.4.6.3.3 Cuff closures/construction

See A.4.2.4.

A.4.7 Requirements for system leakage

For proper and accurate performance, the leakage rate of the sphygmomanometer system as a whole should be low enough to permit the system to meet the requirements for accuracy and repeatability. The recommended rate of pressure release established by the AHA is 2 mmHg/s to 3 mmHg/s. This rate should be controllable by a valve. These criteria can be satisfied if the leakage rate remains below 1 mmHg/s for the entire system.

A.5 Tests

The methods provided in section 4 of the standard are referee tests intended for use in ascertaining device compliance with the requirements of section 4. The methodology specified for design verification of overall system efficacy is not intended for quality assurance purposes, because it is complex and time-consuming. The other methods of section 4 might be suitable for purposes of quality inspection, but it is not intended that these tests shall be used for lot-to-lot quality assurance.

The onset of muffling is the best index of diastolic pressure for children (according to the *Report of the Second Task Force on Blood Pressure Control in Children* [Task Force, 1987]). Furthermore, in some individuals, the end of Phase 4 (cessation) can be as difficult to determine as its onset (muffling). In a large proportion of children, Phase 5 occurs at a value that is below the clinically apparent diastolic value.

If the stethoscope bell is not pressing upon the artery and sounds are still heard at zero or at very low pressure levels, Phase 4 should be used. If the subject is excluded from the study, a statement should be provided in the instruction manual that the instrument might not be appropriate for use with children.

B.2 General considerations in using the auscultatory technique for verification of overall system efficacy of electronic sphygmomanometers

It is recommended that all automated (electronic) devices that indirectly measure arterial blood pressure be capable of providing simultaneous, same-arm measurements with standard auscultatory equipment (Figure B.2).

Because of individual differences among patients and in the proficiency of operators, testing should incorporate techniques designed to reduce the errors influenced by such variables. Qualified personnel who have undergone training with tapes or other methods on blood pressure measurement techniques should do all testing. As specified in 5.4.5.1.1.B, the nonautomated sphygmomanometer used in the comparison testing should comply with 4.4.A, except that its maximum measurement error should not exceed 1 mmHg at the temperature of the test. Both the measurement design and results should be documented and available for inspection. The results of such testing (on a population of at least 85 subjects) should yield a mean difference in simultaneous measurements no greater than ± 5 mmHg, with a maximum standard deviation of 8 mmHg (4.4.5.B).

Numerous studies have questioned the accuracy of automated monitors in pregnant women. If a manufacturer indicates that its device is intended for use with pregnant women, data should be provided that establishes the accuracy in that patient population.

B.3 Procedure

1) The cuff should be placed on the bare upper arm over the brachial artery of the subject and wrapped snugly so as to eliminate any residual air in the bladder. For auscultatory devices, the microphone should be removed from the cuff and placed over the brachial artery at least 1.5 cm above the antecubital fossa. It is best if the microphone is covered with an adhesive pad to ensure good skin contact and avoid noise artifact from the observer's stethoscope, as long as it doesn't interfere with the manufacturer's recommendations.

2) The cuff should be inflated rapidly to 100 mmHg while the radial pulse is palpated. Stepped inflations of 20 mmHg should continue until the radial pulse has been occluded by the cuff pressure. This occluding pressure should be recorded and the cuff deflated. A sufficient time should elapse (at least 60 s) to allow the return of normal circulation.

3) The cuff should then be inflated to a pressure about 30 mmHg higher than the previously recorded occluding pressure, and the bleed valve should be opened to allow deflation at a rate of 2 mmHg to 4 mmHg per heartbeat or 3 mmHg/s. For automatic devices which do not allow for deflation rates in this range, it might not be possible to perform same-limb measurements simultaneously with cuff/bladder manual auscultation. In such cases, same-limb sequential measurements are preferable to contralateral simultaneous measurements. The manufacturer should describe the method used for appropriate testing to validate the automated device against manual sphygmomanometry.

   NOTE—Check that upon opening the valve at the upper pressure range, the initial escape does not exceed the above deflation rate.

   The valve should be manipulated in such a manner as to continue a linear deflation rate of 2 mmHg to 4 mmHg per heartbeat throughout the measurement period. (As the pressure in the cuff decreases, the valve opening should be changed to ensure this linear rate.)

4) With the stethoscope placed over the brachial artery distally, systolic pressure should be recorded when the first Korotkoff sound is detected. Diastolic pressure is recorded at the onset of either Phase 4 or Phase 5 of the Korotkoff sounds, or under other conditions, depending on the device's principle of operation. Great care should be taken to avoid movement of the stethoscope during the measurement, as the device's microphone or oscillometric sensor (depending on the type of device) can inadvertently sense the movement as noise or Korotkoff sounds.

B.4 Major sources of error

Major sources of error for the auscultatory technique include:

— **Inappropriate cuff/arm relationship.** For most adult upper arms, the correct ratio of bladder width to limb circumference is 0.4 (see normative reference 2.5). If the arm is greater than 35 cm in circumference, this bladder would be too small and the blood pressure would be overestimated. If the arm circumference is less than 25 cm, this bladder would be too large and the blood pressure would be underestimated.

— **Stethoscope or transducer not over the brachial artery.** Too much or too little pressure applied to the head of the stethoscope.

— **Patient's arm and back not supported correctly.** Inadequate time allowed for the patient to relax and the blood pressure to stabilize.

— **Inadequate hearing acuity.** This is a critical point, and all skilled observers should have an audiogram prior to the study.

— **Rapid cuff deflation.** As an example of the problem associated with rapid cuff deflation, assume that a patient's systolic pressure is actually 149 mmHg at a given time and that the heart rate is 60 beats/min. Below are pressure recordings, by two hypothetical operators, that illustrate how the cuff deflation rate can contribute to measurement error:

Deflation rate per second:	10 mmHg	3 mmHg
Cuff pressure 150 mmHg:	No K sound	No K sound
First K sound produced:	140 mmHg	147 mmHg

The first operator, using a 10 mmHg/s deflation rate, recorded a systolic pressure of 140 mmHg (9 mmHg below the actual pressure of 149 mmHg); the second operator, using a correct deflation rate (3 mmHg/s), recorded a systolic pressure of 147 mmHg (2 mmHg below actual).

Measurements made from reference sphygmomanometers should be made to the nearest 1 mmHg. This is intended to limit small differences between test and reference methods on account of conventional rounding to the nearest 2 mmHg and allow controlled deflation at 3 mmHg/s or per heartbeat. Automated devices typically measure to the nearest 1 mmHg.

calibrated with the same mercury or digital manometer as the invasive transducer. All calibration records should be kept on a multichannel strip-chart recorder or computerized data collection system with analog or waveform capabilities. The static calibration of both the invasive and noninvasive devices should be within ± 2 mmHg of the reference, and the dynamic calibration (i.e., the frequency-response determination of the invasive device) should be flat (within ± 3 dB) to at least 10 times the fundamental frequency (minimum of 16 Hz), or the frequency response and damping coefficient pair should meet the dynamic requirements proposed by Gardner (1981). In order to achieve this frequency response, the external blood pressure transducer shall be connected to the intra-arterial catheter by stiff tubing, which should be as short as possible, and the entire system shall be completely devoid of air bubbles.

The blood pressure transducer shall be kept at the same level as the blood pressure cuff to avoid hydrostatic effects—for every 1.3 cm of difference in vertical height between the pressure transducer and the arm around which the cuff is wrapped, an offset error of 1 mm difference in measured pressure will result. During each measurement by the noninvasive device, a strip-chart or other computerized recording system should be recording the intra-arterial pressures and analog signals from the noninvasive device (if these are available). Although it is possible to make simultaneous invasive and noninvasive measurements without using a multichannel strip-chart recorder or other computerized recording system, its use is encouraged for the following reasons.

1) The actual intra-arterial systolic and diastolic pressures should be read from the permanent recording, rather than from the display on the intravascular recording device. The accuracy of systolic and diastolic pressure indicators on most monitors is difficult to verify and almost always involves some type of averaging so that the displays will not change too rapidly for clinical use. On some monitors, the selection of systolic and diastolic pressures is accomplished by finding the maximum and minimum pressures over a period of seconds, resulting in very misleading displays if there is much intra-arterial pressure fluctuation. Therefore (and because the chart recorder or computerized system will have been previously calibrated with the system), the reproducibility of readings from the chart recorder or computerized system is better than that for readings from the invasive monitor's digital or analog display.

2) During measurement, it is possible that a gross arrhythmia or artifact due to movement can distort the intra-arterial pressure wave, rendering the determination invalid for comparison purposes. If a continuous, real-time recording of intravascular waveform is used, these artifacts are usually recognized at the time of occurrence, whereas they might never be recognized if only a digital or analog display is used with the invasive system.

3) Electronic signals often associated with the operation of a particular noninvasive device can be recorded simultaneously on other channels of the strip-chart recorder or computerized system. Artifacts caused by patient movement or outside interference usually will become quite obvious upon viewing the chart or computerized record.

4) The permanent record generated by the simultaneous recording of invasive and noninvasive measurements can allow the researcher or manufacturer to devise ways of improving the accuracy of the noninvasive device or enhancing its ability to function in the presence of artifact.

5) In a comparative analysis of the accuracy of the noninvasive and invasive devices, the amount of variability in the patient blood pressure shall be known. This information easily can be obtained from the strip-chart or computerized recordings. The beat-to-beat variability during a noninvasive recording should be calculated. This variability is a source of minor error in the comparisons between the device and the standard.

6) During the study, any deterioration in the waveform recorded by the intra-arterial catheter should be quickly noted and appropriate corrective measures taken immediately (e.g., flushing or adjusting the position of the catheter).

7) The permanent record of each simultaneous determination serves as a source document for further review or inspection.

Multiple readings for each patient should be made as specified in 4.4.5.1.B. At either the beginning or end of each recording session, the following minimum information should be recorded: the patient's identifier, sex, age, height, weight, and arm circumference; the arm on which the occluding cuff was placed; the size of the occluding cuff used; the patient's position, physiologic state, and temperature; and any difficulties encountered.

C.3 Data collection

The most important aspect of data collection is the specification of the intra-arterial pressure during a determination. The measurement obtained from the noninvasive device is subtracted from the intra-arterial measurement to obtain the error for that particular determination. One method of specifying the intra-arterial pressure and computing the error is to obtain from a multichannel strip-chart recorder or computerized system the actual waveforms of the systolic and diastolic pressures at the instant measured by the noninvasive device. The difference between the intra-

arterial pressure recorded and the noninvasive measurement is then calculated. This is only possible if synchronized recordings have been obtained. Another method is to specifically time the period of measurement of the noninvasive device and note this with an event marker on the recording for the intra-arterial pressure. At 3 mmHg/s cuff deflation, the measurement of blood pressure by the noninvasive device ordinarily takes 45 s to 60 s. The intra-arterial beats from the first 15 s of cuff deflation can be averaged to obtain the reference value for systolic pressure, and the last 15 s of cuff deflation can be averaged to obtain the reference value for diastolic pressure. The error of this method has been calculated to be 0.2 ± 3 mmHg for diastolic and 0.6 ± 2 mmHg for systolic. This method is appropriate if the automated device uses markers for systolic and diastpressure that are independent of the mean pressure.

In an alternative method, the highest and lowest values of intra-arterial pressures should be those recorded during the time it takes for the instrument under test to perform a measurement. For example, the systolic (or diastolic) blood pressure reference value obtained by an automated instrument requiring 10 s for measurement should be compared for agreement with the minimum and maximum intra-arterial values over the same 10 s. This method is suggested, particularly for automated monitors that first determine the mean arterial pressure and then determine systolic and diastolic pressure based on the measurement of mean arterial pressure (MAP). Since the measurement of blood pressure is based on the analysis of the oscillometric envelope obtained over the entire determination, the use of the range of reference values of that same time period is indicated.

Of the two methods, the second is far easier to implement and is generally acceptable. Either method requires simultaneous ipsilateral measurements for the greatest level of precision. As pressures can differ in different limbs, simultaneous contralateral measurements are not generally recommended. The need for simultaneous ipsilateral measurements requires the use of a catheter inserted through an artery that is not restricted when the cuff is inflated.

Other methods also might be appropriate. Whichever method is used should be justified as part of the description provided by the manufacturer.

The comparison of intra-arterial blood pressure also should be performed against the mercury column or other accepted means of pressure determination in each subject to obtain an estimate of error between the clinical measurement of blood pressure and intra-arterial blood pressure. This error can be used as a frame of reference for the error obtained by the device. If the device error is in excess of the clinician's error, then the device might be considered unacceptable for clinical use. If the device error is the same or less than the clinician's error, then the device would be considered acceptable for clinical use.